

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

SECURITIES AND EXCHANGE
COMMISSION,

Plaintiff,

v.

DAVID JOHNSTON,

Defendant.

Civil Action No. 16-10607-NMG

ORAL ARGUMENT REQUESTED

*Leave to File in Excess of 20 Pages
Granted on April 12, 2019*

**DEFENDANT'S MEMORANDUM OF LAW IN SUPPORT OF HIS RULE 50(b)
MOTION FOR JUDGMENT AS A MATTER OF LAW OR FOR A NEW TRIAL**

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REQUEST FOR ORAL ARGUMENT

Pursuant to Local Rule 7.1(d), and in order to assist this Court in evaluating the parties' positions, Defendant respectfully requests oral argument on the pending motion.

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Pursuant to Fed. R. Civ. P. 50(b) and 59(a), Defendant David Johnston renews his motion for judgment as a matter of law on all of the claims asserted by Plaintiff Securities Exchange Commission (SEC), and moves in the alternative for a new trial. The Court should enter judgment for Mr. Johnston because the SEC failed to establish two essential elements of its claims: (1) that Mr. Johnston had a duty to disclose the “omitted” information, and (2) that he acted with the requisite culpability.¹ In the alternative, the Court should vacate the judgment and order a new trial (1) on all claims, because the jury instructions did not sufficiently apprise the jurors of the law regarding the essential element of a duty to disclose, and consequently enabled the SEC to confuse the jury by conflating that element with the independent element of materiality, or (2) on the Section 17(a)(2) claim, because the Court’s final instructions to the jury authorized it to find Mr. Johnston liable even though the record lacked any evidence to show that he had personally obtained money or property by means of his conduct.

ARGUMENT

I. The Court Should Grant Judgment as a Matter of Law to Mr. Johnston.

A. The Court Should Grant Judgment as a Matter of Law on the Claims Under Section 10(b) and Rule 10b-5 of the Exchange Act and Section 17(a) of the Securities Act.

The SEC has a simple—albeit hopelessly flawed—theory of the case: that Mr. Johnston committed securities fraud by omitting from several SEC filings and other public statements the fact that, during AVEO’s “pre-NDA meeting” with the Food and Drug Administration (FDA) in

¹ Mr. Johnston filed a timely Rule 50(a) motion before the case was submitted to the jury. ECF 205. The memorandum supporting that motion identified three failed elements: (1) culpability, (2) duty to disclose, and (3) “that [Mr. Johnston] or AVEO made material misstatements.” ECF 206 at p. 1. Mr. Johnston has *not* abandoned the third issue. As the Court will see, however, when the SEC opposed the Rule 50(a) motion, and then when it argued the case to the jury, it glossed over the very real distinction between materiality and the duty to disclose. By conflating these distinct elements, the SEC conflated the issues, and both of them will therefore be dealt with here under the heading of the duty to disclose.

2012, the FDA had “recommended that [AVEO] conduct a second adequately powered randomized trial in a population comparable to that in US.” Nov. 6, 2018, Trial Tr. (attached as Exhibit A to Aff. of J. Sylvia) at 16:24-17:1 (SEC Opening Statement); Nov. 20, 2018, Trial Tr. at 30:10-31:16 (attached as Exhibit B to Aff. of J. Sylvia) (SEC Closing Argument). According to the SEC: (1) Mr. Johnston “should . . . have disclosed the FDA’s recommendation” because of “how important [it] was,” *id.* at 32:9-13, and (2) Mr. Johnston acted recklessly or with fraudulent intent in omitting the information. The first contention is wrong as a matter of law, and the second lacked sufficient evidentiary support to allow the jury’s verdict to stand.

1. Mr. Johnston Had No Duty to Disclose the FDA’s Recommendation.

Because this is an omissions case, the SEC has the burden of proving that Mr. Johnston had a *duty to disclose* the FDA’s recommendation. From the outset, however, the SEC has refused to distinguish between the duty to disclose and the distinct element of materiality. For example, when it opposed Mr. Johnston’s motion for summary judgment, the SEC argued that a triable issue existed as to this element because a jury could find that the omitted information was *material* to investors. ECF 108 at p. 15 (“The FDA’s recommendation was material such that disclosure was warranted.”). The Court, unfortunately, accepted this erroneous formulation. *SEC v. Johnston*, 310 F. Supp. 3d 265, 272 (D. Mass. 2018) (ruling that a trial was required on duty to disclose because “the SEC has raised a genuine issue as to the materiality of the FDA’s recommendation.”).

At trial, the SEC doubled down on conflating materiality and the duty to disclose. It argued repeatedly and exclusively that Mr. Johnston had a duty to disclose the FDA’s recommendation because, “[i]n legal terms, the FDA’s recommendation was material.” Nov. 20, 2018, Trial Tr. at 31:12-13. Posing the issue in the form of a question—“Should David Johnston have disclosed the FDA’s recommendation?”—counsel for the SEC purported to find the answer

in (and only in) the recommendation's materiality: "Witness after witness and document after document showed you how important the FDA's recommendation was." *Id.* at 32:9-13. Again and again, the SEC argued to the jury that the recommendation was "important," *id.* at 33:7, that it was "material," *id.* at 33:21, that it "mattered," *id.* at 34:6-7, that it "was material information, no question about it," *id.* at 35:9-10, that it was "important" and "material," *id.* at 36:3, that it was "the kind of information that would be really important to investors when deciding whether to buy or sell AVEO stock," *id.* at 37:6-8, that it "was a big deal," *id.* at 37:20-21, and that it "was a really big deal." *Id.* at 40:21. Not once, however, did the SEC ever suggest to the jury that it had any basis *other* than materiality on which to find that Mr. Johnston had a duty to disclose.

a. Mr. Johnston Had No Duty to Disclose Interim Feedback from the FDA.

The claims under Sections 10(b) and 17(a) fail as a matter of law because the only evidence the SEC has relates to the putative materiality of the FDA's recommendation, but a duty to disclose does not arise simply because the omitted information was material. The First Circuit long ago established that "materiality and duty to disclose are distinct elements of any allegation of securities fraud." *Backman v. Polaroid Corp.*, Nos. 89-11711, 89-1172, 1990 U.S. App. LEXIS 787, at *14 (1st Cir. Jan. 23, 1990), *withdrawn and substituted opinion*, 910 F.2d 10 (1st Cir. 1990) (en banc); *see also Roeder v. Alpha Industries, Inc.*, 814 F.2d 22, 26 (1st Cir. 1987). As the SEC itself repeatedly emphasized, information is *material* insofar as it is or might be important to *investors*. Absent insider trading or a statutory command, on the other hand, a duty to disclose arises only where disclosure is "necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading," *Roeder*, 814 F.2d at 24—that is, only when "the omitted fact is material *to the statement* in that it alters the meaning of the statement." *In re Raytheon Sec. Litig.*, 157 F. Supp. 2d 131, 150 (D. Mass. 2001)

(emphasis added) (citation omitted). The SEC’s unremitting focus on the putative “importance” of the FDA’s recommendation, therefore, was misplaced and misleading: even if the recommendation *was* “a really big deal,” the claims against Mr. Johnston required the SEC to prove the distinct proposition that disclosing the recommendation was “necessary” to make AVEO’s statements “not misleading.”

Context is always critical to this inquiry, since investors, when attending to an issuer’s public pronouncements, take each statement made, “whether of fact or of opinion, in light of all its surrounding text, including hedges, disclaimers, and apparently conflicting information,” and also take “into account the customs and practices of the relevant industry.” *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 135 S. Ct. 1318, 1330 (2015); *see also* 17 C.F.R. § 240.10b-5(b) (duty to disclose arises only when omitted information was necessary to make statements not misleading “in light of the circumstances under which they were made”).

Context is especially important in cases like this one, moreover, because according to the SEC, the FDA recommendation merely “increased the risk that Tivo would not be approved for sale” on the basis of a single phase 3 trial. Nov. 6, 2018, Trial Tr. at 12:1-3 (SEC Opening). Generally speaking, there is no duty to disclose information that at worst increases the “possibility that an event affecting the company” might occur. *In re Bos. Sci. Corp. Sec. Litig.*, 686 F.3d 21, 27 (1st Cir. 2012). In such cases, disclosure of a contingent risk isn’t just *unnecessary* to make the statements made *not* misleading; premature disclosure could itself be misleading to investors, inducing them to overestimate the likelihood that the risk will actually occur. This is especially likely to happen when the information concerns a risk that, while remote, would be highly *material* to the company if it came to pass. A company may thus “behave ‘irresponsibly’ if it issues an ominous warning about an uncertain risk that ‘had not yet

been adequately investigated.’” *Id.* at 31 (quoting *N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 58 (1st Cir. 2008)).

Few categories of corporate information could be simultaneously more interesting to investors and more inherently uncertain than the contents of a company’s “regulatory back-and-forth” with the FDA during the lengthy and complicated process of developing a new drug. *Fire & Police Pension Ass’n of Colo. v. Abiomed, Inc.*, 778 F.3d 228, 244 (1st Cir. 2015). The courts have repeatedly recognized that “interim FDA feedback” does not “express a binding agency decision and is subject to change as the FDA and pharmaceutical companies work together to develop viable clinical trials and approvable licensing applications.” *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 542 (S.D.N.Y. 2015). Because “[t]here must be some room for give and take between a regulated entity and its regulator,” *Abiomed*, 778 F.3d at 244, the courts have consistently “rejected claims of material omissions where pharmaceutical companies did not reveal procedural or methodological commentary, or other interim status reports, received from the FDA as to drugs under review.” *See Sanofi*, 87 F. Supp. 3d at 541-42 and cases cited therein.

The courts have rejected such claims, moreover, on duty-to-disclose grounds, holding that even though such information may be intensely interesting to investors, companies engaged in the drug-development process have “no legal obligation to loop the public into each detail of every communication with the FDA,” *Corban v. Sarepta Therapeutics, Inc.*, 868 F.3d 31, 40 (1st Cir. 2017), no duty to disclose the “normal risks associated with drug approval,” *Gen. Partner Glenn Tongue v. Sanofi*, 816 F.3d 199, 212 (2d Cir. 2016), and “no duty to report [their] ongoing discussions with FDA during the review process.” *In re Biogen Sec. Litig.*, 179 F.R.D. 25, 37 (D. Mass. 1997) (citation omitted). “Managers . . . are entitled to investigate for a reasonable time, until they have a full story to reveal,” *Higginbotham v. Baxter Int’l, Inc.*, 495 F.3d 753, 761 (7th

Cir. 2007), and a duty to disclose therefore arises only after the agency has communicated something that could fairly be called a “final decision,” *Kader v. Sarepta Therapeutics, Inc.*, No. 1:14-cv-14318-ADB, 2016 U.S. Dist. LEXIS 46025, at *55 (D. Mass. Apr. 5, 2016), which may occur where the FDA’s position will “necessarily prevent the regulatory approval or the marketing of the drug,” *In re AstraZeneca Sec. Litig.*, 559 F. Supp. 2d 453, 470 (S.D.N.Y. 2008), or where it is “tantamount to a statement that [the drug] could not or would not obtain timely FDA approval.” *Sanofi*, 87 F. Supp. 3d at 541; *see also In re Genzyme Corp. Sec. Litig.*, 754 F.3d 31, 42 (1st Cir. 2014) (company had no duty to disclose critical FDA comments about results of plant inspection until agency later sent Complete Response Letter that “crystallized the relevance” of the inspection results by stating that FDA would withhold approval until issues with plant were addressed).

The rule against imposing a duty to disclose interim regulatory feedback should apply here. It is no distinction to argue, as the SEC has in the past, that the cases cited in the preceding section are inapposite “because Aveo chose to disclose certain of its FDA communications.” ECF 108 at p. 15 n.9. The principle at issue has been applied in this Circuit to cases, like this one, in which a defendant chose to disclose some but not all of its communications with the FDA. *See, e.g., Corban*, 868 F.3d at 36, 40 (“[D]efendants had no legal obligation to loop the public into each detail of every communication with the FDA,” even though company *had* made partial disclosures of agency communications and plaintiffs alleged that the disclosures “were misleadingly rosy and selectively omitted further detail that would have better conveyed a picture of a highly dubious FDA.”); *Kader*, 2016 U.S. Dist. LEXIS 46025, at *12, 15-16, 55 (defendants had no duty to disclose FDA request for independent reassessment of trial data because “there was no final decision to communicate—merely interim feedback in the context of

an ongoing dialogue,” even though plaintiffs alleged that a company press release had selectively quoted an FDA guidance letter to convey a false impression about the agency’s position).

When applied, moreover, the rule in question will preclude the SEC’s claims as a matter of law, since there is no dispute about the contingent nature of the FDA’s recommendation. *See* Nov. 20, 2018, Trial Tr. at 38:6-8 (“The Commission agrees, the FDA did not require that AVEO conduct a second trial between May, 2012, and April, 2013.”). The SEC has never been able to do anything more than sneer at this critical fact, *id.* at 38:9-11 (“Mr. Johnston wants to turn this into an English lesson about the difference between ‘require’ and ‘recommend.’”), because all of the relevant evidence shows it to be true. If the FDA’s recommendation in May 2012 necessarily prevented Tivo’s approval, or was tantamount to a statement that the drug would not be approved, then the FDA would not subsequently have (1) characterized the overall-survival trend as a “review” issue at the pre-NDA meeting (May 2012), (2) declined to issue a “Refusal to File” and accepted the NDA for filing on the basis of a single phase 3 trial (September 2012), (3) issued a “74-Day Letter that again indicated only that the data from the single trial would be a “review issue,” but made no demand for a second trial (December 2012); (4) assured AVEO that it had not yet made a decision on the need for a second pre-approval trial (March 2013), or (5) asked the Oncologic Drugs Advisory Committee (ODAC) to provide “advice on whether [the] single trial is sufficient to support approval . . . or whether an additional trial is necessary before considering marketing approval” (May 2013). Trial Ex. 11 (attached as Exhibit C to Aff. of J. Sylvia), at AVEO_SEC000182950.² The “complete picture,” in other

² *See e.g.*, Nov. 7, 2018, Trial Tr. (attached as Exhibit D to Aff. of J. Sylvia) at 62:5-10 (Mr. Eck testifying it was unclear how the FDA’s recommendation would impact the filing or approval); *id.* at 66:3-67:3 (testifying that receipt of the Day 74 letter was “good news” because the FDA had accepted the NDA for review); *id.* at 96:11-15 (Mr. Fitzsimmons testifying that FDA’s response on timing and design of the proposed second trial “was unclear”); Nov. 13,

words, never became “apparent” here. *Genzyme*, 754 F.3d at 44. The known and disclosed risk of non-approval persisted, but the likelihood that it would occur because the FDA *might require* a second pre-approval trial remained unsettled and uncertain throughout the period in question, and thus a duty to disclose the agency’s recommendation never ripened.

b. Mr. Johnston Had No Duty to Disclose Information That Did Not Conflict with AVEO’s Public Statements and That Demonstrably Did Not Lead Investors in the Wrong Direction.

The outcome would not change, however, even absent the specific rule applicable to interim agency feedback, because the more general principles for determining whether a duty to disclose exists require the courts to assess whether disclosure was “necessary in order to make the statements made . . . not misleading.” 17 C.F.R. § 240.10b-5(b). Even though the more general approach lacks the bright lines supplied by the context-specific principle, the calculus is essentially the same: if the SEC’s view prevails, and an issuer “decides to publish the mere fact, it will be faced with a subsequent obligation to supply details. If, to avoid this, it says nothing, but discloses some good news, then the good news without the bad will be misleading for

2018, Trial Tr. (attached as Exhibit E to Aff. of J. Sylvia) at 68:7-11 (Dr. Slichenmyer explaining that as late as March 2013, the FDA had not determined whether any additional trials would be required for approval); *id.* at 128:20-22 (Mr. Johnston testifying that “it was unclear whether [the FDA was] going to approve” the NDA); Nov. 14, 2018, Trial Tr. (attached as Exhibit F to Aff. of J. Sylvia) at 38:2-39:2 (Mr. Johnston testifying that AVEO had submitted questions to the FDA in July 2012 but had not received any answers on the design or timing of recommended second trial); *id.* at 193:19-22 (Dr. Young testifying that AVEO “wanted to know when [the FDA] wanted [a second trial], if they wanted it, and we wanted to know what the nature of the trial was. And we never got an answer to either one of those questions.”); Nov. 15, 2018, Trial Tr. (attached as Exhibit G to Aff. of J. Sylvia) at 79:2-9 (Dr. Berkenblit testifying that although FDA told AVEO they needed a second study, “it was never clear to [her] what they actually meant in terms of when to conduct the study and exactly what the study would look like. [AVEO] never got clarity on that.”); Nov. 16, 2018, Trial Tr. (attached as Exhibit H to Aff. of J. Sylvia) at 68:6-14, 82:8-23 (Mr. Butt testifying that the “FDA is the ultimate boss” and he would “assume they would tell a company” if they are required to do another trial, and acknowledging that the FDA was still undecided as of April 30, 2013, “whether another trial [was] required” and that he believed that “at some level” the ODAC could have come back and said that one trial is sufficient for approval).

incompleteness. It would take a Ulysses to navigate this Scylla and Charybdis.” *Backman*, 1990 U.S. App. LEXIS 787, at *91-92 (Aldrich, J., dissenting).³

Because the purpose of the securities laws is not to put corporations and their representatives between a rock and a hard place, the case law says that, in this context, “[m]isleading must mean misleading in fact, or by implication, within the terms of the disclosure and not mere omission of other facts that might be considered material by the market.” *Id.* at *88. Moreover, since misleading “means to lead in the wrong direction,” *id.* at *88-89, it is not enough to say merely that the omission rendered the statements made “incomplete.” *Backman*, 910 F.2d at 16 (en banc) (requirement that voluntary disclosures be “complete and accurate . . . “does not mean that by revealing one fact about a product, one must reveal all others that, too, would be interesting, market-wise, but means only such others, if any, that are needed so that what was revealed would not be ‘so incomplete as to mislead.’”). An incomplete statement becomes misleading only if, “due to its incompleteness, the statement *affirmatively led the plaintiff in a wrong direction . . .*” *In re Synchronoss Sec. Litig.*, 705 F. Supp. 2d 367, 419 (D.N.J. 2010) (emphasis in original) (citation omitted).

Thus, in order for a plaintiff to win an omissions case like this one, it must prove that the omitted information conflicted with the statements made. *Omnicare*, 135 S. Ct. at 1321 (registration statement may be actionable if omitted facts “conflict with what a reasonable investor . . . would take from the statement itself . . .”). Or, to put it another way, the plaintiff must prove that the defendant’s statements “affirmatively create[d] an impression of a state of

³ Although Judge Aldrich made these comments in a dissent to the panel opinion, they should not be treated as a “minority report” since the matter was taken up en banc and Judge Aldrich’s position ultimately prevailed (and, in fact, Judge Aldrich authored the opinion of the full Court). *Backman*, 910 F.2d at 11 (en banc).

affairs that differ[ed] in a material way from the one that actually exist[ed].” *Brody v.*

Transitional Hosps. Corp., 280 F.3d 997, 1006 (9th Cir. 2002); *see also McDonald v. Kinder-Morgan, Inc.*, 287 F.3d 992, 999 (10th Cir. 2002) (affirming dismissal of securities-fraud claim where omitted information “does not alter the accuracy of the information actually disclosed”).

That did not happen here. The SEC failed to show—and did not bother to argue—that the omission of the FDA’s recommendation altered the accuracy of anything that AVEO disclosed, or that the recommendation conflicted with anything the company said. AVEO and Mr. Johnson disclosed, among other things: (1) all relevant and available data from the TIVO-1 study; (2) that the data showed a slightly negative trend in overall survival for patients randomized to tivozanib; (3) that the FDA had expressed concern about this trend, and had told AVEO that it presented a review issue which could impede the filing of the New Drug Application (NDA) for tivozanib; (4) that, even if the FDA accepted and filed the NDA, the data would also present a review issue for approval; (5) that the FDA generally requires the efficacy of a drug to be demonstrated in two adequate and well-controlled clinical trials; (6) that the FDA might require AVEO “to conduct additional phase 3 clinical trials of tivozanib in order to gain approval”; and (7) that the “bad news scenario” would occur if, at the end of the review process, the FDA concluded that AVEO’s explanation for the adverse trend “sounds plausible but we would like to see a confirmatory study before you start marketing this.”

All of this information was just as true and just as accurate in the absence of the FDA’s recommendation as it would have been if the recommendation had been disclosed, and it is of no legal consequence that disclosing the recommendation would have added something—even something “interesting to investors”—to the inventory of available information about the risk of non-approval. As the Supreme Court has held and the Second Circuit has emphasized, an

omission is not “misleading” simply because the undisclosed information reflected “a risk above and beyond the normal risks” facing the company. *Tongue*, 816 F.3d at 212 (citing *Omnicare*, 135 S. Ct. at 1329). Just as materiality creates no duty to disclose, neither does the fact that investors “perhaps would have acted otherwise had the feedback been disclosed” *Id.*

The record shows, moreover, that even without disclosure of the FDA’s recommendation, investors were *not* affirmatively led in the wrong direction by the statements that AVEO and Mr. Johnston made. AVEO’s stock price dropped by nearly 27% on August 2, 2012—the day on which AVEO disclosed the FDA’s concerns about the TIVO-1 data (while allegedly “omitting” the agency’s recommendation). The movement of the market alone is a strong indication that the “statements made” here were not misleading, but actively pointed investors in the *right* direction.

No investors testified otherwise. Indeed, no investors testified for the SEC at all. Instead, the SEC presented testimony from two industry analysts who were presumably called as proxies for the investing public—Thomas Wei and Adnan Butt. Neither Mr. Wei nor Mr. Butt, however, gave the jury any evidentiary basis for a finding that they were affirmatively led in the wrong direction by AVEO and Mr. Johnston’s statements.

Mr. Wei, for his part, clearly was led in the right direction by what AVEO had disclosed. In particular, he testified that the FDA’s expression of concern to AVEO was “critical” information, Nov. 6, 2016, Trial Tr. at 125:13-16, and that this disclosure alone “fundamentally shifted the whole perspective around the data.” *Id.* at 70:21-22. As a consequence of what AVEO *did* say to the investing public on August 2, 2012, Mr. Wei “ended up lowering [his] price target significantly and also lowered [his] rating from a buy to a hold.” *Id.* at 87:17-20. This was an unusual occurrence, *id.* at 90:22, and it reflected Mr. Wei’s judgment—formed without the

benefit of the FDA’s recommendation—that it was “very unclear how the FDA will judge the situation.” *Id.* at 91:9-10.

Mr. Wei was, however, clear about one thing: that AVEO’s disclosures had highlighted the risk that the FDA would “take a purist approach and merely see AVEO’s arguments as hypothesis generating but requiring a confirmatory study.” *Id.* at 95:3-5; Trial Ex. 113 (attached as Exhibit I to Aff. of J. Sylvia). He wrote those words on August 3, 2012, a day after the company had disclosed the FDA’s concerns (but not its recommendation), and he wrote them because it was apparent to him—on the basis of the information already available to him—that while AVEO’s explanations for the overall survival data “might be good theories, . . . in order to prove the theory, you would just need to run a trial the correct way and see whether or not the overall survival numbers were the same in both arms.” Nov. 6, 2016, Trial Tr. at 95:24-96:3. Far from being led in the wrong direction, then, Mr. Wei followed the company’s statements to precisely the possibility that AVEO and Mr. Johnston are supposed to have concealed: the risk that tivozanib would not be approved for sale without a second confirmatory trial.⁴

2. The Court Should Grant Judgment as a Matter of Law Because Mr. Johnston Did Not Act with a Culpable State of Mind.

The Section 10(b) and Rule 10b-5 claim, as well as any claim asserted under Section 17(a)(1), require the SEC to prove that Mr. Johnston acted culpably, with the state of mind known as “scienter.”⁵ In this context, “scienter” is “a mental state embracing intent to deceive,

⁴ Mr. Butt may not have been as quick on the uptake as Mr. Wei, but he gave no indication of being misled. After agreeing that drug development “is a risky business,” Nov. 16, 2018, Trial Tr. at 11:4, Mr. Butt acknowledged that the questions he asked AVEO’s representatives during the investor conference call on August 2, 2012 reflected the fact that “it seems like I believed that more studies may be needed,” *id.* at 16:12-13, and that one of the risks that he advised his clients about after the conference call was that an advisory committee meeting was more likely. *Id.* at 79:18-22.

⁵ The SEC made its Securities Act claim generally under “Section 17(a),” without specifying whether the claim was under Section 17(a)(1), (a)(2), or (a)(3). ECF 42 at ¶ 90. If the

manipulate, or defraud.” *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 319 (2007) (citation omitted). Proof of “a high degree of recklessness” may also suffice, *Miss. Pub. Emps. Ret. Sys. v. Bos. Sci. Corp.*, 649 F.3d 5, 20 (1st Cir. 2011) (citation omitted); however, “[r]ecklessness, as used in this context, ‘does not include ordinary negligence, but is closer to being a lesser form of intent.’” *Abiomed*, 778 F.3d at 240 (quoting *Greebel v. FTP Software, Inc.*, 194 F.3d 185, 188 (1st Cir. 1999)); *see also Novak v. Kasaks*, 216 F.3d 300, 312 (2d Cir. 2000) (recklessness is “a state of mind ‘approximating actual intent, and not merely a heightened form of negligence’” (quoting *Novak v. Kasaks*, 997 F. Supp. 425, 430 (S.D.N.Y. 1998))). The SEC has failed to create a jury issue on this element as well. “Compelling evidence of scienter most often includes ‘clear allegations of admissions, internal records or witnessed discussions’” suggesting that defendants knew they were withholding “vital information.” *In re Biogen Sec. Litig.*, 193 F. Supp. 3d 5, 44 (D. Mass. 2016). There is no such evidence here. To be sure, “other ‘facts and circumstances indicating fraudulent intent’ . . . may also combine to satisfy the scienter requirement,” *id.* at 46, but insofar as it bears on the issue of culpability, the evidence in this case uniformly undermines—and taken as a whole the record negates—the requisite inference. Broadly speaking, the circumstantial evidence falls into three categories, showing (1) the lack of a clear-cut duty to disclose, (2) a willingness to disclose adverse information as long as its relevance had sufficiently crystallized and its disclosure did not threaten to confuse investors, and (3) Mr. Johnston’s (and AVEO’s) adherence to good corporate-governance practices.

claim was asserted under subsections (a)(2) or (a)(3), then the SEC must prove negligence. *See Aaron v. SEC*, 446 U.S. 680, 695-96 (1980).

a. The Lack of a Clear-Cut Duty to Disclose Undermines Any Potential Inference of Scienter.

The weakness of the SEC’s case on the element of a duty to disclose, discussed above, also diminishes the putative inference of scienter. The strength of the culpability element in a securities-fraud case frequently depends on the strength of the case regarding other elements; for example, as the First Circuit has noted, “the marginal materiality of an omitted fact ‘tends to undercut the argument that defendants acted with the requisite intent . . . in not disclosing it.’” *In re Ariad Pharms. Sec. Litig.*, 842 F.3d 744, 750 (1st Cir. 2016) (citation omitted). Putative inferences of scienter are likewise vitiated by the absence of “facts indicating a clear duty to disclose.” *Kalnit v. Eichler*, 264 F.3d 131, 144 (2d Cir. 2001); *see also Borochoff v. GlaxoSmithKline PLC*, No. 07-cv-5574, 2008 U.S. Dist. LEXIS 38784, at *25-26 (S.D.N.Y. May 9, 2008) (finding no scienter where studies did not show a “decisive” link between defendant’s drug and cardiovascular risks, and the record therefore did not indicate “a clear duty to disclose” the results).

The alleged duty to disclose in this case was anything but clear. Even if the Court believes that the jury could have found such a duty here, the issue is a close call at best. As noted, a duty to disclose feedback from the FDA during the drug-application process will not arise unless and until the agency renders a final decision, or at least says something that is tantamount to a final decision or that necessarily prevents marketing approval. *See* ECF 268 at p. 7 (noting “that Johnston did face factual or legal ambiguities” with respect to the FDA’s recommendation).

In this case, however, “a series of actions by the FDA . . . communicated that timely agency approval was possible” at all points along the relevant timeline. *Sanofi*, 87 F. Supp. 3d at 533. The minutes of the pre-NDA meeting said that the results of the single phase 3 study would

be a filing and a review issue, but the FDA thereafter accepted AVEO's application for filing, issued a "Day 74" letter, assured AVEO that it had not yet made a decision on the need for, or timing of, a second study, and ultimately submitted the key question to the Advisory Committee. Meanwhile, AVEO consulted with two experts in the regulatory process, both of whom assured the company (and Mr. Johnston) that the application was viable; and as the study data matured, and the clinical analysis continued, AVEO and Mr. Johnston received positive signs, indicating that the company would in fact be able to demonstrate to the FDA's satisfaction that the apparent adverse trend in overall survival was merely an artifact of the study's design. Thus, even as the FDA indicated by its actions that its "recommendation" had not yet ripened into anything that approached a requirement, it became increasingly reasonable for Mr. Johnston to believe that tivozanib "continued to be on the path towards [FDA] approval." *Genzyme*, 754 F.3d at 42 (affirming dismissal on scienter grounds, despite failure to disclose FDA criticism of plant conditions that ultimately caused FDA to withhold approval, where there were also "significant factors that pointed to [drug's] approval" at the time of the alleged omissions).

b. The Extent and Impact of AVEO's Disclosures Belie Any Potential Inference of Scienter.

The First Circuit has made it clear that "when defendants do not divulge the details of interim 'regulatory back-and-forth' with the FDA, that alone cannot support an inference of scienter . . . when the defendants *do* provide warnings in broader terms." *Kader v. Sarepta Therapeutics, Inc.*, 887 F.3d 48, 59 (1st Cir. 2018) (emphasis in original) (quoting *Abiomed*, 778 F.3d at 243-44)). Thus, for example, in *Abiomed*, the First Circuit held that any potential inference of scienter was "undercut" by disclosures that stated that the FDA might disagree with the company's position and that the company might therefore face adverse significant consequences. 778 F.3d at 243. Such disclosures simply were "not the actions of a company bent

on deceiving investors as to their future earnings prospects.” *Id.*; *see also Kader*, 887 F.3d at 59-60 (inference of scienter was undercut by disclosure that FDA had concerns about data from defendant’s clinical trial).

The record shows that AVEO, with Mr. Johnston’s active participation, similarly “provide[d] warnings in broader terms” about the status and prospects of its NDA. Both before and after the pre-NDA meeting, all of AVEO’s filings with the SEC described the specific possibility that the FDA might require AVEO “to conduct additional phase 3 clinical trials of tivozanib in order to gain approval” Trial Ex. 1 (attached as Exhibit J to Aff. of J. Sylvia) at p. 49 (Form 10-K for year ending 12/31/11); Trial Ex. 4 (attached as Exhibit K to Aff. of J. Sylvia) at p. 40 (Form 10-K for year ending 12/31/12); Trial Ex. 5 (attached as Exhibit L to Aff. of J. Sylvia) at pp. 50-51 (Form 10-Q for quarter ending 6/30/12); Trial Ex. 10 (attached as Exhibit M to Aff. of J. Sylvia) at p. 44 (Form 10-Q for quarter ending 9/30/12). These possibilities were conspicuously disclosed in the company’s Form 10-K and Form 10-Q under the heading of “Risk Factors.”

Insofar as the FDA’s recommendation at the pre-NDA meeting marginally elevated the already-disclosed risk that additional clinical trials would be needed in order to gain regulatory approval, AVEO’s subsequent public statements accurately reflected the change. Trial Ex. 4 at p. 40 (Form 10-K for year ending 12/31/12); Trial Ex. 5 at pp. 50-51 (Form 10-Q for quarter ending 6/30/12); Trial Ex. 10 at p. 44 (Form 10-Q for quarter ending 9/30/12). In its securities filings after the pre-NDA meeting, AVEO continued to disclose the possibility that the FDA would require an additional trial before approval. *Id.* In its August 7, 2012, Form 10-Q, AVEO disclosed, in its discussion of “Risk Factors” that AVEO:

cannot be certain as to what type and how many clinical trials the FDA, or equivalent foreign regulatory agencies, will require us to conduct before we may

successfully gain approval to market tivozanib. Prior to approving a new drug, the FDA generally requires that the efficacy of the drug be demonstrated in two adequate and well-controlled clinical trials. In some situations, the FDA approves drugs on the basis of a single well-controlled clinical trial. If the FDA or EMA determines that our phase 3 clinical trial results are not statistically significant or do not demonstrate a clinically meaningful benefit and an acceptable safety profile, or if the FDA or EMA requires us to conduct additional clinical trials of tivozanib in order to gain approval, we will incur significant additional development costs, commercialization of tivozanib would be prevented or delayed and our business would be adversely affected.

Trial Ex. 5 at pp. 50-51. The company also disclosed both the interim data from the TIVO-1 trial, which showed the slightly negative trend in overall survival of patients randomized to tivozanib, and the fact that the “FDA has expressed concern regarding the overall survival trend in the TIVO-1 trial and has said that it will review these findings at the time of the NDA filing as well as during the review of the NDA.” *Id.*; Trial Ex. 10 at p. 44 (Form 10-Q for quarter ending 9/30/12); Trial Ex. 4 at p. 40 (Form 10-K for year ending 12/31/12). These facts, identified as additional “Risk Factors” in AVEO’s securities filings, conspicuously increased the indicated probability of the particular regulatory outcomes that the SEC has accused Mr. Johnston of hiding from investors.

AVEO did not limit its disclosure of this information to its formal SEC filings. The survival trend, the concerns expressed by the FDA staff, and the fact that the survival data would present a “review” issue for both filing and approval, were also disclosed in the press release issued by AVEO to announce its SEC filing in August 2012, and in the accompanying conference call with investors and analysts. *See* Trial Ex. 92 (attached as Exhibit N to Aff. of J. Sylvia) at p. 8 (Aug. 2, 2012 Form 8-K); Trial Ex. 76 (attached as Exhibit O to Aff. of J. Sylvia) at AVEO_SEC000016269 (Transcript of Aug. 2, 2012 2Q12 Fin. Results Conf. Call). Mr. Johnston was not just on board with these additional disclosures; he, along with several colleagues, *recommended* them to management. Nov. 14, 2018, Trial Tr. at 37:4-18; 39:4-14.

There was no pushback: all of AVEO's top managers agreed with this view and approved the additional disclosures, *id.*, and after Mr. Johnston personally presented the matter to AVEO's audit committee, its members agreed to the disclosures as well. *Id.* at 53:16-57:8.

Moreover, even as it explicitly disclosed the increased risks of a Refusal to File or rejection on the merits, AVEO implicitly raised the indicated probability of an adverse regulatory outcome in another way: by muting its previously-expressed optimism about the likelihood of a *favorable* outcome. Before the pre-NDA meeting, the company's securities filings had informed investors that, while the FDA generally requires efficacy to be demonstrated in two clinical trials, one trial will sometimes suffice. Because all of the licensed drugs in tivozanib's class had been approved on the basis of a single phase 3 trial, AVEO had been hopeful that tivozanib would be treated the same way: "we believe we will be required to conduct only a single phase 3 clinical trial" Trial Ex. 1 at p. 49 (Form 10-K for year ending 12/31/11). In its filings after the pre-NDA meeting, however, AVEO dropped this expression of confidence, giving investors an additional indication that the risk of that particular adverse outcome had increased. Nov. 14, 2018, Trial Tr. at 216:3-10.

The record thus shows not only that AVEO and Mr. Johnston provided "warnings in broader terms" to the investing public, but "that the most relevant and disappointing aspect" of the TIVO-1 study—the unfavorable trend in overall survival and the concerns expressed by the FDA about that trend—had "entered the marketplace." *Biogen*, 179 F.R.D. at 39. In *Biogen*, Chief Judge Saris granted summary judgment to the defendants where the company disclosed that its drug had failed to meet a primary endpoint, but omitted the fact that the drug had also failed to meet any of its 24 secondary endpoints. *Id.* The omission was deemed inactionable in light of evidence that Biogen's stock had dropped after the allegedly-incomplete disclosure, and

that key analysts had downgraded the stock even in the absence of the omitted information. *Id.* The market certainly got the message here. AVEO's stock price dropped by nearly 27%—the largest one-day decline in company history, Nov. 14, 2018, Trial Tr. at 41:2—after AVEO disclosed the FDA's concerns about the TIVO-1 data (while allegedly “omitting” the agency's recommendation). *Id.* at 40:21-24.

c. AVEO and Mr. Johnston's Adherence to Corporate-Governance Protocols and Reliance on Advice from Independent Parties Undermines Any Potential Inference of Scienter.

Nothing in the record supports an inference of conscious intent to defraud, and there is no evidentiary basis for a claim of “reckless” scienter, either. Any number of people here saw what Mr. Johnston saw, when he saw it—the TIVO-1 data, the minutes of the pre-NDA meeting, and the substance of AVEO's proposed disclosures. Among others, they included AVEO's lawyers, the members of its Executive Committee, the members of its Audit Committee, and the members of its Disclosure Committee. *See* Nov. 14, 2018, Trial Tr. at 33:12-36:10; 58:1-60:3; 64:4-10; 66:21-67:5. These were all sophisticated actors, all with their own obligations to the company and its investors. Later on, AVEO shared the same information with a number of independent parties who had a strong interest in full and accurate disclosure—namely, the underwriters of the 2013 public offering and the underwriters' attorneys—and none of them criticized the disclosures that had been made or saw the need to supplement those disclosures with information about the recommendation. *Id.* at 118:8-123:9; Trial Ex. 440 (attached as Exhibit P to Aff. of J. Sylvia) at p. 5 (Jan. 23, 2013 Letter from WilmerHale to JP Morgan); Trial Ex. 441 (attached as Exhibit Q to Aff. of J. Sylvia) at p. 2 (Jan. 23, 2013 Letter from Ropes & Gray to JP Morgan). Thus, on this uncontroverted record, a reasonable jury could not find that Mr. Johnston knew of or recklessly disregarded a “significant risk” of non-approval and therefore acted with scienter

when he did not disclose the fact that the FDA had recommended a second study during the May 11, 2012 pre-NDA meeting. *See In re Bos. Sci. Corp. Sec. Litig.*, 708 F. Supp. 2d 110, 126 (D. Mass. 2010) (finding that plaintiffs failed to establish sufficient evidence to prove corporate scienter when the record demonstrated “a measured effort, in furtherance of a prudently cautious approach, by a corporation seeking to understand and correct the limitations of a product and to respond with appropriate adjustments.”).

Indeed, Mr. Johnston should prevail as a matter of law even under the negligence standard. Negligence requires proof that the defendant did not exercise ordinary care under the circumstances, and the record here shows that AVEO and Mr. Johnston were in fact extraordinarily careful in making sure that they satisfied any potential disclosure requirements. First, the fact that AVEO disclosed anything at all about its interactions with the FDA (e.g., the agency’s concerns about the survival data) shows that the company took an especially prudent approach to its *legal* obligations, exceeding the requirements of the case law, cited in Section I.A.1.a of this memorandum, that imposes no duty to disclose such provisional feedback from the FDA.

In addition, the record shows, without any qualification, that Mr. Johnston and AVEO’s management team punctiliously discharged their *corporate-governance* obligations in framing the company’s disclosures to investors. Every one of the corporate statements was vetted before the fact both internally and externally, by financial experts, by disclosure specialists, by regulatory advisors, by inside and outside counsel, and by the members of AVEO’s Executive Committee and Audit Committee. Nov. 14, 2018, Trial Tr. at 33:12-36:10. In obtaining all of these levels of scrutiny, input, and approval, moreover, Mr. Johnston behaved exactly as he would have done with any other public disclosure by the company. *Id.* at 33:10-34:19; 35:19-

36:10; 50:20-24. The company's scrupulous adherence to its standard governance protocols offers additional evidence that Mr. Johnston "acted in good faith and/or with due care in making the alleged misrepresentations" *SEC v. Present*, No. 14-cv-14692-LTS, 2017 U.S. Dist. LEXIS 120351, at *2-3 (D. Mass. July 31, 2017).

B. The Court Should Grant Judgment as a Matter of Law on the Rule 13a-14 Claim.

The SEC's third claim against Mr. Johnston is for violating Exchange Act Rule 13a-14 by making "materially false" certifications of AVEO's quarterly and annual financial reports in 2012 and 2013. On its face, the rule only "requires that for every report filed under Section 13(a) of the Exchange Act, including Form 10-Q and 10-K financial reports, each principal executive and principal financial officer of the issuer must sign a certification as to the accuracy of the financial statements within the report." *SEC v. Jensen*, 835 F.3d 1100, 1112 (9th Cir. 2016).

Consequently, "[t]here is some debate as to whether the requirement to 'sign a certification' creates a separate cause of action if the documents are certified as true but actually contain misrepresentations." *SEC v. E-Smart Techs.*, 31 F. Supp. 3d 69, 86 (D.D.C. 2014) (citation omitted). The Ninth Circuit has held that it does, *Jensen*, 835 F.3d at 1113 (holding that Rule 13a-14 "includes an implicit truthfulness requirement"), but even if the Ninth Circuit is right, the rule would merely "create liability for false statements," *id.*, and thus it would not support a claim based on the alleged omission of information that the defendant had no duty to disclose. Moreover, although the majority in *Jensen* "decline[d] to reach the question of the mental state required for a violation" of Rule 13a-14, *id.* at 1113 n.6, the concurring opinion emphasized that, because "the concept of falsity embodies a mental element," *id.* at 1117 (Bea, J., concurring), the Rule should be applied so that "liability for false certification . . . may lie only where a CEO or CFO acts with knowledge or at least recklessness as to the falsity of a

certification.” *Id.* at 1118; *see also SEC v. Goldstone*, Jury Instructions at 56, No. 12-cv-00257, Dkt. 573 (D.N.M. 2016); *SEC v. Bankatlantic Bancorp, Inc.*, Jury Instructions at 20, No. 12-cv-60082, Dkt. 414 (M.D. Fla. Dec. 15, 2014) (requiring that the defendant “knew the certification was false when he signed it”); *SEC v. Furman*, Jury Instructions at *22, No. 08-cv-1620, Dkt. 149 (S.D. Cal. Feb. 25, 2011) (requiring that the “Defendant knew the certification was false”); *SEC v. Life Partners, Holdings, Inc.*, Jury Instructions at *6, No. 12-cv-33 (W.D. Tex. Mar. 12, 2014) (“To establish a violation of Rule 13a-14, the SEC was required to show ... that [the defendant] knew of the misrepresentation or omission when he certified the report.”); *SEC v. Hilger*, No. 06-10012-JGD, 2008 U.S. Dist. LEXIS 123745, at *6 (D. Mass. June 11, 2008) (jury finding defendant violated Section 13(a) because “he knew that the report contained false and misleading statements or omissions”). Because AVEO’s disclosures were accurate and complete, as explained above, and did not omit a material fact necessary to make the report not misleading, the SEC’s Rule 13a-14 claim fails as a matter of law.

II. In the Alternative, the Court Should Grant Mr. Johnston’s Motion for a New Trial.

A. The Court Should Grant a New Trial on All of the SEC’s Claims.

The SEC’s insistence on conflating materiality and duty to disclose has long been a feature of this litigation. The issue first arose when Mr. Johnston moved for summary judgment and the SEC opposed by arguing, with respect to the element of duty to disclose, that “[t]he FDA’s recommendation was material such that disclosure was warranted.” ECF 108 at 15. Although Mr. Johnston pointed out the fallacy in his reply memo, ECF 118 at 4-5, the SEC’s case-in-chief—as the Court has seen—focused on materiality to the exclusion of the kind of evidence that (had it existed) might have properly established a duty to disclose, and foreshadowed its continued reliance on a strategy that threatened to confuse and mislead the jury by amalgamating two distinct legal elements. Mr. Johnston therefore attempted to clarify the

distinction in his Rule 50(a) motion, ECF 206 at 2-3, and then sought to forestall, or at least to mitigate, any jury confusion that the SEC might seek to engender by asking the Court to give the jury one instruction on materiality, ECF 139 at 24 (Proposed Instruction No. 18), and the following, entirely separate instruction on the duty to disclose:

Even if the SEC proves that certain information not disclosed by Mr. Johnston was “material,” in the sense that I have just described to you, it cannot prevail unless it also proves that Mr. Johnston had a duty to disclose the omitted information. Under the law, Mr. Johnston was not required to disclose every piece of non-public information he possessed even if the information was material. Instead, you must consider whether the omitted fact was necessary to make what was disclosed not misleading. In other words, to determine whether Mr. Johnston had a duty to disclose the omitted information, you must determine whether the omitted fact or facts were necessary so that what was revealed would not be so materially incomplete as to mislead.

A defendant, however, has no duty to disclose information where its materiality is uncertain or indeterminate, such as where the information concerns a future event that may or may not occur and it is therefore unclear whether, or how, the information might affect the total mix of facts available to investors. It is not permissible to use hindsight when making this determination; the question is how the picture looked to Mr. Johnston when he made the statements at issue.

You should keep in mind here that the SEC has alleged the omission of information that AVEO received from the Food and Drug Administration about the company’s New Drug Application. Because continuous dialogue between the FDA and the proponent of a new drug is the essence of the new drug application process, a pharmaceutical company and its representatives have no legal obligation to loop the public into each detail of every communication with the FDA, and no duty to report the company’s ongoing discussions with the FDA during the review process. Interim feedback from the FDA does not have to be disclosed unless it expresses a binding agency decision or imposes a mandatory prerequisite for approval.

ECF 139 at 25-26 (Proposed Instruction No. 19) (citations omitted).

The Court rejected this request and instead gave the jury a combined instruction on both materiality and the duty to disclose:

[T]he SEC must prove that Mr. Johnston committed fraud by making one or more statements that were not true when they were made or show that Mr. Johnston failed to disclose a material fact that he had a duty to disclose in order to make the other statements not misleading.

For the SEC to prevail, you must unanimously agree on which statement was untrue or which undisclosed fact was misleading and find that the untrue statement or undisclosed fact was material.

I will now describe the terms “material” and “duty to disclose” in a little more detail. A fact is material if there is a substantial likelihood that a reasonable investor would consider the fact important when making a decision about whether to invest his money in a particular security. In other words, a statement leaves out a material fact if there is a substantial likelihood that a reasonable investor would view the absent fact as significantly altering the total mix of information available. When information merely creates a possibility that an event affecting a company will later occur, materiality will depend upon a balancing of both the indicated probability that the event will occur and the anticipated magnitude of the totality of the company activity.

You cannot find a Defendant liable if he did not have a duty to disclose the information. Information that is disclosed must be complete and accurate, but not all information that is material and nonpublic must be disclosed. Thus, even if an omitted statement was material, a Defendant cannot be liable for securities fraud if there was no duty to disclose the information at issue.

For example, a Defendant does not have a duty to disclose facts that would be interesting to the market, nor must every discussion between a regulated entity and its regulator be disclosed. Rather, a Defendant has a duty to disclose information when it is material and when the fact or facts would need to be revealed so as not to mislead.

Nov. 20, 2018, Trial Tr. at 90:20-93:13.

Mr. Johnston timely objected to the Court’s instruction at the charge conference, *id.* at 105:7-106:3. In particular, he objected (1) to the Court’s decision not to explain to the jury how cases such as *Corban v. Sarepta* hold that there is no duty to disclose uncertain risks arising out of interim communications from regulators such as the FDA, and (2) to the instruction’s failure to draw a distinction between materiality and the duty to disclose—i.e., “to the extent that it didn’t make clear to the jury that the duty to disclose arises only when the statement is material [to investors] *and* that the omitted fact is material to the statement in that it alters the meaning of that statement.” *Id.* at 105:21-106:1 (emphasis added).

The jury instruction was erroneous in large part because of what it did not say. First, by declining to make the requested distinction between materiality to investors and materiality to

statements made, the Court failed to adequately convey the essential principle that “materiality and duty to disclose are distinct elements of any allegation of securities fraud,” *Backman*, 1990 U.S. App. LEXIS 787, at *14, and “was thus incorrect.” *Costa-Urena v. Segarra*, 590 F.3d 18, 25 (1st Cir. 2009) (instruction was incorrect where it did not adequately convey controlling legal principle). This misimpression was only accentuated by the Court’s decision not to give separate instructions on materiality and the duty to disclose, but to combine both elements into a single package.

Second, the instruction failed to convey a second essential principle because it did not—as Mr. Johnston had requested—explain to the jury that, in cases like this one involving regulatory back-and-forth with an agency such as the FDA, no duty to disclose can arise with respect to “interim” communications that convey only contingent positions and thus reflect uncertain risks and outcomes. The Court’s refusal to give such an instruction was reversible error because the requested instruction was (1) correct as a matter of substantive law, (2) integral to an important point in the case, and (3) not substantially incorporated into the charge as rendered. *Cigna Ins. Co. v. Oy Saunatec*, 241 F.3d 1, 8 (1st Cir. 2001).⁶

At bottom, the instruction was both error and harmful error because it effectively memorialized the confusing and misleading conflation of materiality and the duty to disclose that the SEC had introduced into the case. *See Poulin v. Greer*, 18 F.3d 979, 983 n.3 (1st Cir. 1994) (“In reviewing a court’s decision not to give a particular instruction, our duty is to determine

⁶ The Court did not “substantially incorporate” the requested instruction into the charge by telling the jury “nor must every discussion between a regulated entity and its regulator be disclosed.” Nov. 20, 2018, Trial Tr. at 93:9-10. Although this statement might have alerted the jury to the notion that a different rule might *sometimes* apply to communications by a regulator such as the FDA, it left them in the dark as to the substance of that rule and the circumstances under which it would apply.

whether the instructions as given tend to confuse or mislead the jury with regard to the applicable principles of law.”). The abridged instruction at best failed to dispel the confusion sown by the SEC, and at worst actively contributed to it, as evidenced by the extent to which the SEC elided the distinction between materiality and the duty to disclose in its closing argument, and by the jury’s verdict in the face of a record that may have supported an inference of materiality, but that utterly failed to demonstrate the two factual prerequisites to a valid finding of a duty to disclose: (1) that the FDA’s recommendation was not contingent and uncertain, and therefore did not trigger the operation of the *Sanofi* rule, and (2) that the omitted information conflicted with statements that AVEO had made, and that those the statements, when made in the absence of the omitted information, thus affirmatively led investors in the wrong direction.

B. The Court Should Grant a New Trial on the Section 17(a)(2) Claim.

Section 17(a)(2) required the SEC to prove, among other things, that Mr. Johnston “directly or indirectly . . . obtain[ed] money or property by means of” the alleged misconduct. 15 U.S.C. §77q(a)(2). During the proceedings about the proposed jury instructions, an issue emerged about this element of the case. Although the statute on its face requires proof that the *defendant* obtained money or property, at least one District Court had decided that it would be sufficient for the SEC to show that the defendant either (1) personally obtained money, or (2) “obtained money or property for his employer while acting as its agent” *SEC v. Stoker*, 865 F. Supp. 2d 457, 463 (S.D.N.Y. 2012). Other courts disagreed, holding that because to “obtain” an object means to “gain possession of it,” it is not enough to show that a third party, such as the defendant’s employer, reaped a financial benefit from his or her misconduct. *SEC v. Syron*, 934 F. Supp. 2d 609, 638 (S.D.N.Y. 2013); *see also SEC v. DiMaria*, 207 F. Supp. 3d 343, 358 (S.D.N.Y. 2016); *SEC v. Daifotis*, No. C 11-00137, 2011 U.S. Dist. LEXIS 60226, at *26-27 (N.D. Cal. June 6, 2011).

Both at the charge conference and before the case was submitted to the jury, Mr. Johnston made known his objections to a charge that would allow the jury to find the “money or property” element satisfied on the basis of evidence about money obtained by AVEO, not by Mr. Johnston. Nov. 16, 2018, Trial Tr. at 56:24-57:8; Nov. 20, 2018, Trial Tr. at 107:11-20. Initially, the Court did not resolve this issue, and gave an anodyne instruction that simply tracked the language of the statute. Nov. 20, 2018, Trial Tr. at 99:11-16.

The issue re-emerged, however, during the jury’s deliberations. The jury came back to the Court with a question: “[I]f AVEO (company) had ‘obtained money or property,’ could we assume that Johnston also ‘obtained money or property’?” *Id.* at 110:23-111:1. At this point, the Court decided to adopt the reasoning of the District Court in *SEC v. Stoker*, “that a Defendant can be liable if he obtained money for his employer while acting as its agent” *Id.* at 111:9-15. Accordingly, the Court instructed the jury that while it “cannot assume that just because AVEO obtained money or property, that Johnston also did . . . , the Defendant can be held liable if you find by a preponderance of the evidence that he obtained money for his employer while acting as its agent” *Id.* at 119:20-25. Mr. Johnston noted his objections to this instruction. *Id.* at 112:9-113:23, 119:1-5. The jury ultimately found that the element was satisfied. ECF 213 at 2.

The Court should grant Mr. Johnston a new trial on the Section 17(a)(2) claim because the final instruction to the jury was erroneous, and because the error was not harmless. Mr. Johnston acknowledges the absence of controlling authority and the difference of opinion among the courts that have addressed this issue. He submits, however, that the better position is the one adopted by the Southern District of New York in *Syron* and *DiMaria*, and by the Northern District of California in *Daifotis*. The problem with the decision in *Stoker* is that it focused on the

meaning of the wrong word. The Court in *Stoker* reasoned that the “money or property” requirement should be read broadly because “all three prongs of liability under Section 17(a) are preceded by the common modifier ‘directly or indirectly.’” *Stoker*, 865 F. Supp. 2d at 463. As Judge Sullivan correctly recognized in *Syron*, though, this analysis effectively ignores the meaning of a word that appears only in Section 17(a)(2): “obtain.” The plain, dictionary meaning of “obtain” makes it “clear that to obtain an object is to gain possession of it.” *Syron*, 934 F. Supp. 2d at 638. On its face, then, the statute requires proof that the defendant gained possession of money or property by means of his misconduct, and that does not happen in cases in which the only party enriched by the defendant is a third party such as the defendant’s employer.

The error was *not* harmless. Because the parties had stipulated to exclude evidence of stock trades, ECF 136, the jury had no basis upon which to consider whether Mr. Johnston had or had not obtained money or property in that manner. Nor was there any evidence to suggest that Mr. Johnston’s compensation from AVEO in the second half of 2012 and the first half of 2013 had been linked in any way to anything that the company had obtained by means of the conduct in question. In the absence of such evidence, it is likely that the jury found the “money or property” element satisfied only by evidence of what AVEO had obtained. *See* Nov. 20, 2018, Trial Tr. at 45:20-24, 58:4-6, 60:13-16 (SEC repeatedly emphasizing in its Closing Argument that Mr. Johnston raised \$54,000,000 on behalf of AVEO). Indeed, that is highly likely, because if the jury could have found that Mr. Johnston had personally obtained any money or property, it would not have asked the Court for permission to “assume” that he had done so based only on evidence about what the company had obtained. If it does not grant Mr. Johnston judgment as a matter of law or a new trial on all claims, therefore, the Court should at least grant a new trial on the Section 17(a)(2) claim.

CONCLUSION

For the reasons stated in this memorandum, Mr. Johnston respectfully asks the Court to grant him judgment as a matter of law on all of the SEC's claims; or, in the alternative, to grant him a new trial on all claims, or on the Section 17(a)(2) claim.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) on April 22, 2019.

/s/ John F. Sylvia

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